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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/853,635

Applicant(s)

OLSON, BENGT KRISTER

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on MARCH 21, 2003 as Paper Number 11.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Applicants' Responsive amendment filed 03/21/2003 as paper Number 11 is acknowledged and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 65-88 have been added.
3. Claims 1-64 have been cancelled.
4. Claims 65-88 are pending.

Claims Objection

5. Claims 65, 68 and 75 are objected for the reasons noted below:
 - Claim 65 lacks the intended use (e.g., for oral administration) of the claimed composition.
 - In Claims 68 "*Gingo*" is misspelled. Appropriate correction is required.
 - In Claim 75, "xanthofyll" is misspelled. Appropriate correction is required.

Claim Rejections Under 35 U.S.C. § 112

6. Claims 65-66, 68, 70-71, 74, 78 and 81-88 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - Claims 65-66, 74, 78 and 81-88 are rendered vague and indefinite by the term "extract" in those Claims because this term, in and of itself, does not adequately delineate its metes and bounds. For example, is said extract obtained by extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? Furthermore, in claims where tomato/ cartilage or fish extract is recited, the plant/ animal part (e.g., tomato seed or fruit/ fish bone or cartilage) should also be clearly specified because for e. g., it is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants/herbs, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein. Since the extract/extracts

themselves are clearly essential to the claimed invention, the steps(s) by which the claimed extract/ extracts are obtained are also clearly essential and, therefore, must be recited in the claim language itself. Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "*Cardus mariannum*" in claim 68 is used by the claim to mean "*Carduus mariannus*" which is the accepted botanical synonym for milk thistle (i.e., *Silybum marianum*; see for e.g., Duke, J. et al. Handbook of Medicinal Herbs, 2002, CRC Press, Boca Raton, FL., U.S.A., Page 502, first line of text after the figure). Appropriate correction should be made.
- Claim 70 is rendered vague and indefinite because of the phrase, "ingredients extractable from grape seeds". This phrase, in and of itself does not define its metes and bounds. Appropriate correction is required.
- Claims 81 and 82 are rejected because of the range within range, i.e. broad limitation followed by a narrow limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance for e.g., Claim 82 recites the broad recitation, for example, "0.25-15 mg lycopene and the claim also recites " 0.5-5 mg of lycopene" which is the narrower statement of the range/limitation.
- Claims 81-82 are rendered vague and indefinite by the term "preferably". A broad range or term followed by linking terms (e.g., preferably, may be, for instance,

especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly/set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information).

- Claim 88 is rendered vague and indefinite because of the phrases "slow release" and "normal release" at Line 2. These terms are subjective and therefore, do not establish any metes and bounds to distinguish one term from another. An artisan skilled in the art will not be able to distinguish among the terms as discussed above. It is also not clear how the same composition would simultaneously have both "slow release" and "normal release" components? Applicants are requested to define or clarify the phrases "slow release" and "normal release".

All other claims depend directly from the rejected claims (1, 15 or 20) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

7. in view of applicant's above-cited amendment, rejection to Claims 13, 17, 19, 30, 32, 34-36 and 41 under 35 U.S.C. §112, Second paragraph in Office Action mailed September 23, 2002 (Paper#9) have been withdrawn.

Claim Rejections Under 35 U.S.C. § 102

8. Applicants' arguments regarding the rejection to Claims 13-20, 24 and 32 under 35 U.S.C. §102(b) as anticipated by Greenberg (U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402) in Office Action mailed September 23, 2002 (Paper#9) have been fully considered but are not persuasive for the reasons of record on Page 5 under item 9 of said Office action. In response to art rejections under 35 U.S.C. § 102(b) discussed *supra*, applicant argues that Greenberg's exhaustive list of components comprising the composition that Greenberg teaches does not comprise either lycopene or chondroitin sulphate. Since the examiner-cited reference teaches a composition comprising beta-carotene (see Column 2, Line 63) which is a lipophilic antioxidant according to applicant's own assertion (See Claim 24) and the claim language does not specifically call for lycopene (Claim 24 recites "lipophilic antioxidant comprises a carotenoid selected from the group consisting of α -carotene, β -carotene") as the lipophilic antioxidant, Greenberg's composition teaches a composition comprising a lipophilic antioxidant and chondroitin

sulphate (See Column 3, Line 36 after the word "trypsin"). As discussed *supra*, Greenberg's composition inherently comprises both hydrophilic and lipophilic antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line 37) and beta carotene (i.e., β -carotene)

Claim Rejections Under 35 U.S.C. § 103(a)

9. Claims 65-85 and 88 are rejected under 35 U.S.C. § 103 (a) as obvious over Greenberg (U.S. Patent 5,569,458) in view of Bombardelli et al (EP 0,6559,402) and Kosbab (WO 00/07607).

Claims recite a composition comprising cartilage extract or compounds extractable from cartilage and hydrophilic and lipophilic antioxidants, wherein said antioxidants are obtained from a synthetic or natural source. Said natural source are plant extract components, more specifically oligomeric procyanidol, lycopene and carotenes. The source for said plant extracts are any one of following plants: *Aesculus hippocastanum*, *Cardus marianum*, *Ginkgo biloba*, pine bark, *Silybum marianum*, tomato, *Vaccinium myrtillus* and *Vitis vinifera*.

Greenberg teaches a composition comprising chondroitin sulphate, extracts from *Ginkgo biloba* and *Silybum marianum*, proanthocyanidins, vitamin E and β -carotene (Column 2, Lines 63-67; Column 3, Lines 36-40). Thus, Greenberg discloses a composition comprising cartilage extract compound (e.g., chondroitin sulphate), lipophilic (e.g., vitamin E and β -carotene) and hydrophilic (e.g., proanthocyanidin from red wine grapes and extract of *Ginkgo biloba*) antioxidants.

Greenberg, however, does not disclose in his composition grape seed extract and procyanidole oligomers, different plants as the natural source of antioxidants, different sources of lipophilic antioxidants (e.g., lycopene, xanthophylls, carotenes) and tomato extract as the source of lycopene/lipophilic antioxidants. Furthermore, Greenberg does not distinguish among the hydrophilic and lipophilic antioxidant components of his composition.

Bombardelli et al., teach a composition comprising hydrophilic and lipophilic antioxidants, wherein the sources for hydrophilic antioxidants are: silymarin, proanthocyanidin and procyanidole oligomers extracted from *Aesculus hippocastanum*, *Camelia sinensis*, *Cardus marianum*, *Ginkgo biloba* or *Vitis vinifera*. In said composition the sources for lipophilic antioxidants, among others, are: β -carotene, lycopene and vitamin E

wherein tomato is the source of lycopene (Page 6, Lines 47-53 and Page 7, Lines 1-4). Thus, Bombardelli et al. clearly define the sources of hydrophilic and lipophilic antioxidants in their composition and further disclose that the sources for lipophilic and hydrophilic antioxidants comprising their composition are natural.

None of the prior art references cited *supra* clearly disclose cartilage extract/ cartilage extract components or pine bark extract as the components for their compositions.

Kosbab, however, discloses compositions comprising cartilage or chondroitin sulphate (Page 24, Line 6) and antioxidant containing plant extracts (See e.g., Page 8, Lines 3-4), wherein antioxidants are: carotenoid, flavonoids and Vitamin E (page 43, Lines 1-11). The sources for carotenoids in the said composition are β -carotene, lutein, lycopene, zeaxanthin (Page 24, Lines 24-25) and sources for flavonoids are: extracts of bilberry (i.e., *Vaccinium myrtillus*), *Ginkgo biloba*, grape seed and pine bark (Page 23, Lines 26-32 and Page 24, Lines 10 and 20-21), green tea (i.e., *Camelia sinensis*, See Page 8, Line 4). Said composition has an antioxidant effect (Page 43, Lines 8-9 and Page 44, Lines 10-14).

One having ordinary skill in the art would have been motivated to modify Greenberg's composition (Column 2, Lines 63-67; Column 3, Lines 36-40) according to the beneficial teachings from Bombardelli et al., because Bombardelli et al., remedy the deficiency in Greenberg's teachings of distinguishing between components comprising hydrophilic and lipophilic antioxidants and indicate the natural sources (plant species and extracts from those plant species) for those antioxidants (Page 6, Lines 47-53 and Page 7, Lines 1-4). Kosbab's beneficial teachings (Page 8, Line 4; Page 23, Lines 26-32; Page 24, Lines 6, 10, 20-21 and 24-25; page 43, Lines 1-11 and Page 44, Lines 10-14) remedy the deficiency in Greenberg's and Bombardelli et al.'s teaching by beneficially teaching that cartilage and chondroitin sulphate as components of Kosbab's composition, and further that the composition is also comprised of antioxidants obtained from a variety of natural sources (e.g., plants) and that chondroitin sulphate is one of the extractable compound from cartilage.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Greenberg's composition by incorporating beneficial teachings from Bombardelli et al., and Kosbab, because each one of the cited prior art references teach a composition comprising hydrophilic and lipophilic antioxidants, wherein the sources for those antioxidants are natural (i.e., plant extracts) and Kosbab further

teaches that said composition is comprised of antioxidants and cartilage extract/ components (e.g., glycosaminoglycan) present in cartilage extract.

The concentration of individual antioxidant components or of components obtained from cartilage/cartilage extract in the aforementioned prior art references is either not disclosed or is not the same as in the claimed invention. However, the adjustment of particular conventional working conditions (e.g., concentrations of individual components comprising a given composition or ratios among different components of a composition) is deemed merely a matter of judicious selection and routine optimization of a result oriented parameter, which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Applicants' arguments regarding rejections to Claims 13-27, 29-36 and 41 under 35 U.S.C. §103(a) in Office Action mailed September 23, 2002 (Paper#9) have been fully considered but are not persuasive for the reasons of record at item 11, pages 6-8 of the Office Action cited *supra*. In response, applicants argue the same reasoning as discussed for Claim Rejections Under 35 U.S.C. § 102 (b) *supra* and further argues that applicant's instantly claimed invention is not obvious over examiner cited prior art references because Greenberg's composition is intended to resolve a different condition than that of enhancing collagen synthesis that applicant claims in the instantly claimed invention and that a skilled artisan attempting to develop a treatment for a skin condition would not be benefited with Greenberg's teachings. Applicant also argues that Bombardelli et al. reference does not teach advantage of combining lycopene, lipophilic and hydrophilic antioxidants in their composition for skin conditions. In summary, applicant's arguments are around the fact that Greenberg's composition does not teach lycopene as a component in said composition and that combined teachings from Greenberg, Bombardelli et al. and Kosbab are not applicable for a skin condition.

Applicant's argument regarding deficiencies in Greenberg's composition or compositions that Greenberg, Bombardelli et al. and Kosbab teach have already been

settled in discussion of answering applicant's arguments with regards to rejections under 35 U.S.C. § 102 (b) supra.

In response to applicant's arguments that teachings from examiner cited prior art references do not disclose that their compositions would enhance collagen synthesis or resolve a skin condition and are therefore, not obvious over applicant's instantly claimed invention, the functional intended use of a composition does not materially change a given composition and is accordingly, not given any patentable weight. However, since teachings from examiner cited prior art references disclose a composition comprised of same/similar ingredients as recited in applicant's instantly claimed invention, said invention is obvious over the Examiner cited prior art references.

CONCLUSION

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. No Claims are allowed. However, Claims 86-87 read on a singular synthetic component as the source for antioxidants and if written as an independent claim or part of an independent claim drawn to a specific antioxidant source, may be allowable subject matter.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30A.M. to 6:00 P. M. (Eastern Standard or Daylight Saving time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through

Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kallash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

June 12, 2003



CHRISTOPHER R. TATE
PRIMARY EXAMINER